BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents *will not* correct images, please do not report the images to the Image Problem Mailbox.

REMARKS

This application was filed with original claims 1-61. Claims 48-50 have been canceled without prejudice or admission by Applicants, and in favor of new claims 62-64. In particular, canceled claims 48-50, as originally filed, recite the "use of" particular salts in parenteral vaccines and/or adjuvant compositions. New claims 62-64 specifically recite "methods" for using these salts in such vaccines and compositions. Dependent claims 51-58 have also been amended to depend from the new method claims. In addition, claims 4-9, 11-14, 16-20, 24-29, 31-33, 35-39, 43-47 and 51-60 have been amended to remove multiple dependencies and to conform with the requirement of 37 C.F.R. §1.75. Finally, the specification has also been amended to particularly recite each of the priority applications identified in the Application Data Sheet submitted with this application as filed.

The above amendments do not, therefore, introduce new matter to the application. Entry of the amendments into the file history of this application is respectfully requested.

Respectfully submitted,

Dated: November 26, 2001

Samuel S. Woodley, Ph.D.
Reg. No. 43,287
Agent for Applicants

DARBY & DARBY, P.C.
805 Third Avenue
New York, N.Y. 10022
Phone (212) 527-7700

EXHIBIT A:
AMENDMENTS MADE TO PENDING CLAIMS
SUBMITTED PURSUANT TO 37 C.F.R. § 1.121(c)(1)(ii)

U.S. PATENT APPLICATION SERIAL NO. 09/925,635
ATTORNEY DOCKET NO. 4305/1H520-US1

4. (Amended) A parenteral vaccine formulation according to [claims 1-2] claim 1, wherein the adjuvant is selected from salts formed with oxides, peroxides, hydroxides, carbonates, phosphates, pyrophosphates, hydrogenphosphates, dihydrogenphosphates, sulphates, and/or silicates, and hydrates thereof.

5. (Amended) A parenteral vaccine formulation according to [claims 1-2, and 4] claim 1, wherein the adjuvant is selected from salts formed between Mg, Ca, Ba, Ti, or Zr, and oxide, peroxide, hydroxide, and/or carbonate, and hydrates thereof.

6. (Amended) A parenteral vaccine formulation according to [claims 1-2, and 4-5] claim 1, wherein the adjuvant is selected from salts formed between magnesium and oxide, peroxide, hydroxide, and/or carbonate, calcium and oxide, peroxide, hydroxide, and/or carbonate, barium and oxide, peroxide, hydroxide, and/or carbonate, titanium and oxide, peroxide, hydroxide, and/or carbonate, and zirconium and oxide, peroxide, hydroxide, and/or carbonate, and hydrates thereof.

7. (Amended) A parenteral vaccine formulation according to [claims 1-2, and 4-6] claim 1, wherein the adjuvant is selected from magnesium hydroxide, magnesium carbonate hydroxide pentahydrate, titanium dioxide, calcium carbonate, barium hydroxide, barium peroxide, barium carbonate, barium sulphate, beryllium oxide, calcium sulphate, calcium silicate, dicalcium silicate, tricalcium silicate, calcium pyrophosphate, calcium peroxide, calcium hydroxide, tricalcium phosphate, calcium hydrogenphosphate, calcium dihydrogenphosphate, calcium sulphate dihydrate, magnesium carbonate, magnesium oxide, magnesium dioxide, magnesium sulphate, trimagnesium phosphate, magnesium silicate, dimagnesium trisilicate, magnesium trisilicate, titantium disulphate, zirconium dioxide, zirconium hydroxide, zirconium sulphate, strontium peroxide, and strontium carbonate.

8. (Amended) A parenteral vaccine formulation according to [claims 1-2, and 4-7] claim 1, wherein the adjuvant is selected from magnesium hydroxide, magnesium carbonate hydroxide pentahydrate, and titanium dioxide.

9. (Amended) A parenteral vaccine formulation according to [claims 1-8] claim 1 further comprising an additional adjuvant.

11. (Amended) A parenteral vaccine formulation according to [claims 1-10] claim 1, further comprising pharmaceutically acceptable excipients and/or carriers.

12. (Amended) A parenteral vaccine formulation according to [claims 1-11] claim 1, further comprising diluents, buffers, suspending agents, solubilising agents, pH-adjusting agents, dispersing agents, and/or colorants.

13. (Amended) A parenteral vaccine formulation according to [claims 1-12] claim 1, for intravenous, intramuscular, intraarticular, subcutaneous, intradermal, epicutantous, and intraperitoneal administration.

14. (Amended) A parenteral vaccine formulation according to [claims 1-13] claim 1, wherein the cation of the adjuvant is present in an amount of from about 0.0004 to about 120 M, such as from about 0.004 to about 12 M.

16. (Amended) A parenteral vaccine formulation according to [claims 1-15] claim 1, wherein the adjuvant is magnesium hydroxide.

17. (Amended) A parenteral vaccine formulation according to [claims 1-15] claim 1, wherein the adjuvant is magnesium carbonate hydroxide pentahydrate.

18. (Amended) A parenteral vaccine formulation according to [claims 1-15] claim 1, wherein the adjuvant is titanium dioxide.

19. (Amended) A parenteral vaccine formulation according to [claims 1-15] claim 1, wherein the adjuvant is a combination of magnesium hydroxide and magnesium carbonate hydroxide pentahydrate, magnesium hydroxide and titanium dioxide, magnesium carbonate hydroxide pentahydrate and titanium dioxide, or magnesium hydroxide, magnesium carbonate hydroxide pentahydrate, and titanium dioxide.

20. (Amended) A parenteral vaccine formulation according to [claims 16-19] claim 16 further comprising an additional adjuvant selected from saponins such as Quil A and Qs-21, MF59, MPL, PLG, PLGA, calcium phosphate, and aluminium salts.

24. (Amended) An adjuvant composition according to [claims 21-22] claim 21, wherein the salt is selected from salts formed with oxides, peroxides,

hydroxides, carbonates, phosphates, pyrophosphates, hydrogenphosphates, dihydrogenphosphates, sulphates, and/or silicates, and hydrates thereof.

25. (Amended) An adjuvant composition according to [claims 21-22, and 24] claim 21, wherein the salt is selected from salts formed between Mg, Ca, Ba, Ti or Zr, and oxide, peroxide, hydroxide, and/or carbonate, and hydrates thereof.

26. (Amended) An adjuvant composition according to [claims 21-22, and 24-25] claim 21, wherein the salt is selected from salts formed between magnesium and oxide, peroxide, hydroxide, and/or carbonate, calcium and oxide, peroxide, hydroxide, and/or carbonate, barium and oxide, peroxide, hydroxide, and/or carbonate, titanium and oxide, peroxide, hydroxide, and/or carbonate, and zirconium and oxide, peroxide, hydroxide, and/or carbonate, and hydrates thereof.

27. (Amended) An adjuvant composition according to [claims 21-22, and 24-26] claim 21, wherein the salt is selected from magnesium hydroxide, magnesium carbonate hydroxide pentahydrate, titanium dioxide, calcium carbonate, barium hydroxide, barium peroxide, barium carbonate, barium sulphate, beryllium oxide, calcium sulphate, calcium silicate, dicalcium silicate, tricalcium silicate,

calcium pyrophosphate, calcium peroxide, calcium hydroxide, tricalcium phosphate, calcium hydrogenphosphate, calcium dihydrogenphosphate, calcium sulphate dihydrate, magnesium carbonate, magnesium oxide, magnesium dioxide, magnesium sulphate, trimagnesium phosphate, magnesium silicate, dimagnesium trisilicate, magnesium trisilicate, titantium disulphate, zirconium dioxide, zirconium hydroxide, zirconium sulphate, strontium peroxide, and strontium carbonate.

28. (Amended) An adjuvant composition according to [claims 21-22, and 24-27] claim 21, wherein the salt is selected from magnesium hydroxide, magnesium carbonate hydroxide pentahydrate, and titanium dioxide.

29. (Amended) An adjuvant composition according to [claims 21-28] claim 21 further comprising an additional adjuvant.

31. (Amended) An adjuvant composition according to [claims 21-30] claim 21 further comprising pharmaceutically acceptable excipients and/or carriers.

32. (Amended) An adjuvant composition according to [claims 21-31] claim 21 further comprising diluents, buffers, suspending agents, solubilising agents, pH-adjusting agents, dispersing agents, and/or colorants.

33. (Amended) An adjuvant composition according to [claims 21-32] claim 21, wherein the cation of the salt is present in an amount of from about 0.0004 to about 120 M, such as from about 0.004 to about 12 M.

35. (Amended) An adjuvant composition according to [claims 21-34] claim 21, wherein the salt is magnesium hydroxide.

36. (Amended) An adjuvant composition according to [claims 21-34] claim 21, wherein the salt is magnesium carbonate hydroxide pentahydrate.

37. (Amended) An adjuvant composition according to [claims 21-34] claim 21, wherein the salt is titanium dioxide.

38. (Amended) An adjuvant composition according to [claims 21-34] claim 21, wherein the salt is a combination of magnesium hydroxide and magnesium carbonate hydroxide pentahydrate, magnesium hydroxide and titanium dioxide, magnesium carbonate hydroxide pentahydrate and titanium dioxide, or magnesium hydroxide, magnesium carbonate hydroxide pentahydrate, and titanium dioxide.

39. (Amended) An adjuvant composition according to [claims 35-38] claim 35 further comprising an additional adjuvant selected from saponins such as Quil A and Qs-21, MF59, MPL, PLG, PLGA, calcium phosphate, and aluminium salts.

43. (Amended) An adjuvant according to [claims 40-41] claim 41, wherein the salt is selected from the salts formed with oxides, peroxides, hydroxides, carbonates, phosphates, pyrophosphates, hydrogenphosphates, dihydrogenphosphates, sulphates, and/or silicates, and hydrates thereof.

44. (Amended) An adjuvant according to [claims 40-41, and 43] claim 40, wherein the salt is selected from salts formed between Mg, Ca, Ba, Ti or Zr, and oxide, peroxide, hydroxide, and/or carbonate, and hydrates thereof.

45. (Amended) An adjuvant according to [claims 40-41, and 43-44] claim 40 wherein the salt is selected from salts formed between

magnesium and oxide, peroxide, hydroxide, and/or carbonate,

calcium and oxide, peroxide, hydroxide, and/or carbonate,

barium and oxide, peroxide, hydroxide, and/or carbonate,

titanium and oxide, peroxide, hydroxide, and/or carbonate, and

zirconium and oxide, peroxide, hydroxide, and/or carbonate,

and hydrates thereof.

46. (Amended) An adjuvant according to [claims 40-41, and 43-45] claim 40 wherein the salt is selected from magnesium hydroxide, magnesium carbonate hydroxide pentahydrate, titanium dioxide, calcium carbonate, barium hydroxide, barium peroxide, barium carbonate, barium sulphate, calcium sulphate, tricalcium silicate, calcium pyrophosphate, calcium peroxide, calcium hydroxide, tricalcium phosphate, calcium hydrogenphosphate, calcium dihydrogenphosphate, calcium sulphate dihydrate, magnesium carbonate, magnesium sulphate, trimagnesium phosphate, magnesium silicate, magnesium trisilicate, titantium disulphate, zirconium sulphate, strontium peroxide, and strontium carbonate.

47. (Amended) An adjuvant according to [claims 40-41, and 43-46] claim 40, wherein the salt is selected from magnesium hydroxide, magnesium carbonate hydroxide pentahydrate, and titanium dioxide, or the salt is selected from a combination of magnesium hydroxide and magnesium carbonate hydroxide pentahydrate, magnesium hydroxide and titanium dioxide, magnesium carbonate hydroxide pentahydrate and titanium dioxide, or magnesium hydroxide, magnesium carbonate hydroxide pentahydrate, and titanium dioxide.

51. (Amended) [Use] A method according to [claims 49-50] claim 64, wherein the salt is selected from inorganic salts.

52. (Amended) [Use] A method according to [claims 49-50] claim 64, wherein the salt is selected from organic salts.

53. (Amended) [Use] A method according to [claims 49-51] claim 64, wherein the salt is selected from salts formed with oxides, peroxides, hydroxides, carbonates, phosphates, pyrophosphates, hydrogenphosphates, dihydrogenphosphates, sulphates, and/or silicates, and hydrates thereof.

54. (Amended) [Use] A method according to [claims 49-51, and 53] claim 64 wherein the salt is selected from salts formed between Mg, Ca, Ba, Ti, or Zr, and oxide, peroxide, hydroxide, and/or carbonate, and hydrates thereof.

55. (Amended) [Use] A method according to [claims 49-51, and 53-54] claim 64, wherein the salt is selected from salts formed between magnesium and oxide, peroxide, hydroxide, and/or carbonate, calcium and oxide, peroxide, hydroxide, and/or carbonate, barium and oxide, peroxide, hydroxide, and/or carbonate, titanium and oxide, peroxide, hydroxide, and/or carbonate, and

zirconium and oxide, peroxide, hydroxide, and/or carbonate, and hydrates thereof.

56. (Amended) [Use] A method according to [claims 49-51, and 53-55] claim 64, wherein the salt is selected from magnesium hydroxide, magnesium carbonate hydroxide pentahydrate, titanium dioxide, calcium carbonate, barium hydroxide, barium peroxide, barium carbonate, barium sulphate, beryllium oxide, calcium sulphate, calcium silicate, dicalcium silicate, tricalcium silicate, calcium pyrophosphate, calcium peroxide, calcium hydroxide, tricalcium phosphate, calcium hydrogenphosphate, calcium dihydrogenphosphate, calcium sulphate dihydrate, magnesium carbonate, magnesium oxide, magnesium dioxide, magnesium sulphate, trimagnesium phosphate, magnesium silicate, dimagnesium trisilicate, magnesium trisilicate, titantium disulphate, zirconium dioxide, zirconium hydroxide, zirconium sulphate, strontium peroxide, and strontium carbonate.

57. (Amended) [Use] A method according to [claims 49-51, and 53-56] claim 64 wherein the salt is selected from magnesium hydroxide, magnesium carbonate hydroxide pentahydrate, and titanium dioxide, or wherein the salt is selected from a combination of magnesium hydroxide and magnesium carbonate hydroxide pentahydrate, magnesium hydroxide and titanium dioxide, magnesium carbonate hydroxide pentahydrate and titanium dioxide, or magnesium hydroxide, magnesium carbonate hydroxide pentahydrate, and titanium dioxide.

58. (Amended) A method of generating an immune response in a subject comprising administering to the subject a parenteral vaccine formulation according to [claims 1-20] claim 1.

59. (Amended) [Vaccination] A method for vaccination or treatment of a vertebrate including a human being comprising administering a vaccine formulation according to [claims 1-20] claim 1.

60. (Amended) A process for preparing a parenteral vaccine formulation according to [claims 1-20] claim 1 comprising adding liquid to a dry form of or a pre-formed gel of the salt formed with a Group 2 element of the Periodic Table selected from Mg, Ca, Sr, Ba and Ra, or a Group 4 element of the Periodic Table selected from Ti, Zr, Hf, and Rf, the salt not being calcium phosphate, not being magnesium hydroxide in combination with aluminium hydroxide or aluminium oxide and not being calcium hydroxide in gel combination with zinc hydroxide, lecithin and polyalphaolefine, thereby obtaining an adjuvant composition, and mixing said adjuvant composition with one or more immunogenic substances and optionally pharmaceutically acceptable carriers and/or excipients, thereby obtaining the parenteral vaccine formulation.